

THE CLAIMS

The status of the claims is as follows:

1. (Previously presented) A bioadhesive, controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:
an effective amount of an active ingredient that is a sex hormone,
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer, and
a water soluble polymer,
wherein said composition is formulated in a dry state to progressively hydrate and deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said mammal.
2. (Previously presented) The composition of claim 1, wherein said active ingredient is present in about 50% by weight or less.
3. (Previously presented) The composition of claim 1, wherein said active ingredient is testosterone or progesterone.
4. (Previously presented) The composition of claim 3, wherein said composition is formulated to deliver said active ingredient via the mammal's vaginal cavity.
5. (Previously presented) The composition of claim 3, wherein said composition is formulated to deliver said active ingredient via the mammal's buccal cavity.
6. (Cancelled)
7. (Previously presented) A method of delivering to a mammal a sex hormone, comprising administering said sex hormone via a progressive hydration bioadhesive composition to a mucosal surface of the mammal, wherein said composition is formulated as a dry tablet that includes
 - (a) said sex hormone,
 - (b) a bioadhesive, water insoluble, water swellaable cross-linked polycarboxylic polymer, and
 - (c) a water-soluble polymer.

8-9 (Cancelled)

10. (Previously presented) A method of delivering testosterone to a mammal, comprising administering said testosterone via a bioadhesive, progressive hydration composition through a mucosal surface of the mammal, wherein the composition comprises:
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,
a water soluble polymer, and
said testosterone,
and wherein said method provides a blood serum concentration ratio of testosterone to 5 α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

11-14. (Cancelled)

15. (Previously presented) The composition of claim 1, wherein said composition is formulated to deliver said active ingredient via the mammal's nasal cavity.

16. (Previously presented) The composition of claim 1, wherein said composition is formulated to deliver said active ingredient via said mammal's rectal cavity.

17-18. (Cancelled)

19. (Previously presented) The method of claim 10, wherein said composition is administered through the mammal's buccal cavity.

20. (Previously presented) The method of claim 10, wherein said composition is formulated is administered through the mammal's vaginal cavity.

21-22. (Cancelled)

23. (Previously presented) A bioadhesive, progressive hydration pharmaceutical composition comprising:
testosterone,
a bioadhesive, water insoluble, water-swellaable cross-linked polycarboxylic polymer,
and a water soluble polymer,
wherein said composition is formulated to progressively hydrate and to deliver a therapeutically effective amount of said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

24. (Previously presented) The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

25. (Previously presented) The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

26. (Previously presented) A bioadhesive, controlled, sustained release progressive hydration composition for delivering testosterone to the bloodstream of a mammal, comprising:
a bioadhesive, water insoluble, water swellaable cross-linked polycarboxylic polymer,
a water soluble polymer,
and testosterone,
wherein said composition is formulated to progressively hydrate upon application to a mucosal surface of said mammal and to deliver said testosterone through said mucosal surface, and to provide a blood serum concentration ratio of testosterone to 5 α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

27. (Previously presented) The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

28. (Previously presented) The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

29. (Previously presented) The method of claim 7, wherein said mucosal surface is the mammal's vaginal cavity.

30. (Previously presented) The method of claim 7, wherein said mucosal surface is the mammal's buccal cavity.

31. (Previously presented) A bioadhesive, progressive hydration pharmaceutical composition comprising:
testosterone,
polycarbophil,
and a water soluble polymer,
wherein said composition is formulated to progressively hydrate and to deliver said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

32. (Previously presented) The composition of claim 31, wherein the water soluble polymer is carbomer 974P.

33. (Previously presented) A method of administering testosterone to a mammal, comprising delivery of said testosterone via a progressive hydration bioadhesive composition to a mucosal surface of said mammal, wherein said composition includes

- (a) said testosterone,
- (b) polycarbophil, and
- (c) a water soluble polymer.

34. (Previously presented) The method of claim 33, wherein said water soluble polymer is carbomer 974P.